

<sup>7</sup>  
13. (new) The hair growth tonic of claim <sup>5</sup>~~11~~,  
wherein said lactic acid producing bacteria is *Streptococcus*  
*lactis* or *Lactobacillus bulgaricus*.

A1 <sup>8</sup>  
14. (new) The hair growth tonic of claim <sup>5</sup>~~11~~,  
wherein at least one of said chlorophyll and laurel extract is  
present.

REMARKS

The Official Action of March 28, 2002, and the prior art relied upon therein have been carefully reviewed. The claims in the application are now claims 7-14, and these claims define patentable subject matter warranting their allowance. Accordingly, applicant respectfully requests favorable reconsideration and allowance.

Acknowledgement by the PTO of the receipt of applicant's papers filed under Section 119 is noted.

Claims 1, 2, and 4 have been rejected as anticipated under §102 by Reddy USP 4,797,289 (Reddy) and also as obvious under §103 from this same document. These rejections are respectfully traversed.

With respect to the rejection based on §102, the PTO takes the position that it may disregard applicant's preamble which is said to be only an intended use. With respect, this

is not correct under the present circumstances, because the preamble in the present application defines what the invention is, not its intended usage.

In this regard, Reddy discloses a yogurt drink including lactic acid bacteria. A "drink" is something in which a person "drinks", not a composition which someone applies to his or her head. In this regard, applicant notes that a "hair growth tonic" is what the present composition is, and its intended use is something else. Thus, what the claimed composition is (which includes its purpose), and what its intended use is, are two different things.

Stated another way, a hair growth tonic is a defined material, which is a topical composition as opposed to a drink. There differ fundamentally with respect to site of application (the head rather than internally), a different purpose, and different basic properties. It is very important for the person skilled in the art whether or not the present invention relates to a drink or a hair growth tonic.

Applicant respectfully notes that the case law supports applicant's position. In this regard, the examiner's attention is respectfully invited to *In re Steppan et al*, 156 USPQ 143, 147. Here, the preamble of claim 25 read as follows:

25. An acid phosphate of a condensation product of...

The appellants argued that the expression "condensation product" defined "what the acid phosphate is", and the court reversed the PTO's rejection. Also see the somewhat analogous case of *In re Garner*, 162 USPQ 221, 223, where in effect the Court held that the claim language "interbonded one to another by interfusion" defined the structure of the product. See also *In re Bulloch et al*, 203 USPQ 171, 174 (CCPA 1979).

There should be no doubt that, as a general rule, all subject matter recited in a claim must be given full weight; and, consequently, any rejection based on anticipation requires that the reference relied upon show each and every feature claimed. A sometimes exception is when the claim preamble only calls for an intended use. The leading case in this area is *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951).

*In Kropa v. Robie*, the court reviewed thirty seven of its own prior decisions in cases where it had determined whether or not the claim preamble must be given effect. The court stated:

..., in those *ex parte* and interference cases where the preamble to the claim or count was expressly or by necessary implication given the effect of a limitation, the introductory phrase was deemed essential to point out the invention defined by the claim or count. In the latter class of cases, the preamble was considered necessary to give life, meaning and vitality to the claims or counts. Usually, in those cases, there inhered in the article specified in the preamble a problem

which transcended that before prior artisans and the solution of which was not conceived by or known to them. The nature of the problem characterized the elements comprising the article, and recited in the body of the claim or count following the introductory clause, so as to distinguish the claim or count over prior art.

The same situation exists in the present case. Particular problems exist in growing hair which clearly have no relevance with respect to a drink.

In other words, using the language of *Kropa v. Robie*, inherent in a hair growth tonic is the solution of "a problem which transcended that before prior artisans and the solution of which was not conceived by or known to them" as regards the drink of Reddy. The introductory clause is therefore "essential to point out the invention defined" by the remainder of applicant's claims.

The examiner may wish to consider some other cases which are more recent than *Kropa v. Robie*. Attention is therefore first invited to the case of *Perkin-Elmer v. Computervision*, 221 USPQ 669, 675 (Fed. Cir. 1984), where the introductory clause of claim 1 called for a "unity magnification catoptric image-forming system..." In giving weight to such recitation, the court stated:

The system of claim 1 is one of unity magnification and is image forming. Those limitations appear in the preamble, but are necessary to give meaning to the claim and properly define the invention. [citations omitted]

In *Loctite v. Ultraseal*, 228 USPQ 90, 91-93, the introductory portion of claim 1 of the '012 patent read as follows:

1. An anaerobic curing sealant composition adapted to remain in a liquid, non- polymerizing state... .

The court stated:

Although it appears in the preambles of the '012 patent claims, the term "anaerobic" breathes life and meaning into the claims and hence is a necessary limitation to them. [citation omitted]

The holdings of the lower court were vacated, and the case was remanded.

Attention is next invited to *In re Stencel*, 4 USPQ2d 1071 (Fed. Cir. 1987) where the introductory clause of claim 1 called in part for a "driver for setting a joint of a threaded collar, ... the collar having plastically deformable lobes on its longitudinal exterior ..., the driver comprising: ... .".

In reversing the rejection, the Court stated:

We conclude that it would not have been obvious to [provide the applicant's invention] unless one had in mind the purpose taught by appellant. This purpose, set forth in the claims themselves, "is more than a mere statement of purpose; and that language is essential to particularly point out the invention defined by the claims." [citations omitted; bracketed material added]

Similarly, in the present case, the purpose of the present applicant is not to be found in Reddy; this purpose, set forth in applicant's claims, "is essential to particularly point out the invention defined by the claims".

Lastly, attention is respectfully invited to *Corning Glassworks v. Sumitomo Electric*, 9 USPQ2d 1962, 1965-66 (Fed. Cir. 1989). Here, claim 1 of the '915 patent recited an "optical wave guide comprising..." The Court stated:

In this case, the question of anticipation turns on claim interpretation, ... . [citation omitted]  
If the claims are given Sumitomo's suggested interpretation, the [prior art] patent anticipates [claims 1 and 2 of the '915 patent]; otherwise, it does not. In particular, the dispute focuses on the interpretation and effect of the words "An optical wave guide" in claim 1. ... . [bracketed words added]

Sumitomo argued that the fiber of the prior art patent could "inherently" function as a "waveguide", and therefore the words "An optical waveguide" should be ignored because "the preamble is not a limitation when it merely states a purpose or *intended use* and the remainder of the claim completely defines the invention". (Italics in the court decision)

In affirming the lower court's decision of validity (no anticipation), the court stated in part as follows:

The effect preamble language should be given can be resolved only on review of the entirety of the [disclosure] to gain an understanding of what the inventors actually invented and intended to encompass by the claim. Here, the 915 specification makes clear that the inventors were working on the particular problem of an effective optical communication system not on general improvements in conventional optical fibers. To read the claim in light of the specification indiscriminately to cover all types of optical fibers would be divorced from reality. The invention is restricted to those fibers that work as waveguides as defined in the specification, which is not true with respect to fibers constructed with the limitations of paragraphs (a) and (b) only. Thus, we conclude that the claim preamble in this instance does not merely state a purpose or intended use of the claimed structure [citation omitted]. Rather, those words do give "life and meaning" and provide further positive limitations to the invention claimed [citations omitted]. Thus, contrary to Sumitomo's argument, the core and cladding limitations set out in paragraphs (a) and (b) are not the only limitations of the claim [citation omitted]. The claim requires, in addition, the particular structural relationship defined in the specification for the core and cladding to function as an optical waveguide.

Similarly, the introductory clause of applicant's claims is also a requirement of applicant's invention. The Court continued:

Viewed in this manner, the fact that the [prior art] luminescent fiber could inherently transmit information for a few meters becomes irrelevant. The [prior art] patent does not disclose all the limitations of the claimed "optical

waveguide" as that term is structurally defined by the '915 inventors.

The examiner should be guided by the above quoted words of the Federal Circuit from *Corning Glass Works v. Sumitomo Electric*.

Reddy discloses only a yogurt drink including lactic acid bacteria, but does not disclose a hair growth tonic containing any lactic acid bacteria or any fraction thereof. Furthermore, Reddy does not suggest use of a culture filtrate of a lactic acid bacteria, after crushing the cellular walls of the lactic acid bacteria, as an active agent of a hair growth tonic.

The \$102 rejection should be withdrawn, and such is respectfully requested.

As regards the \$103 rejection based on Reddy, it is clear that the person of ordinary skill in the art would not be taught by Reddy to use the Reddy yogurt drink as a hair growth tonic. Moreover, it furthermore would not have been obvious from Reddy to use a culture filtrate obtained after crushing the cellular walls of the lactic acid bacteria.

The rejection based on \$103 should be withdrawn, and such is respectfully requested.



Claims 1, 2, 4 and 5 have been rejected under §102 as anticipated by Silvestrini USP 4,749,684 (Silvestrini). This rejection is respectfully traversed.

Silvestrini is directed to a method of increasing the rate of linear growth of hair by administration of gelatin over a long period of time (e.g. the abstract). The gelatin is administered internally, not applied to the head. Thus, Silvestrini relates to a method wherein "gelatin (jelly)" is added "to foodstuffs at a dosage of 8-16 g per daily portion." (Col. 1, lines 9-11).

However, it turned out that such a high dosage rate of gelatin could not be tolerated by some patients. Thus, at column 2, commencing at line 50, the following text appears:

A second study was undertaken identical to the first one... with the exception of the way in which the experimental substances were administered... In the second study, both gelatin and starch were administered not any longer in the form of capsules but by mixing them in an ordinary jar of commercial yogurt. This was to be eaten in the morning, for breakfast,...

Again, as with Reddy discussed above, the yogurt in the case of Silvestrini was eaten, totally inconsistent with the present invention which is directed to a hair growth tonic. The commentary made above with respect to Reddy is equally applicable here.

Moreover, also as pointed out above with respect to Reddy, Silvestrini does not disclose the use of a culture filtrate after crushing the cellular walls of the lactic acid bacteria. Silvestrini does not anticipate applicant's claims.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-6 have been rejected as obvious under \$103 from Matsuoka JP '009 in view Chizick et al, USP 5,972,345 (Chizick). This rejection is respectfully traversed.

Matsuoka is the closest prior art in applicant's view because Matsuoka, unlike the prior art discussed above, at least relates to a hair tonic composition. While the English language abstract is somewhat ambiguous (e.g. it is unclear whether both the liquid extract of Chinese anis and a powder thereof are essential components, or only one of these is an essential component), the hair tonic of Matsuoka appears to be a product resulting from the mixture of at least (1) most importantly a liquid extract produced by immersing and boiling dried Chinese anis in a solvent, (2) milk and (3) *Lactobacillus*, and permitting the mixture to "rest until the mixture has separated into a liquid and a solid". What fraction is then used? What is in that fraction? Is the *lactobacillus* in liquid fraction or the solid fraction? Is the *lactobacillus* an active component?

It is not seen that the English language abstract of Matsuoka teaches the person of ordinary skill in the art that *lactobacillus per se* has any activity with regard to either "preventing falling-off and gray hair and remarkably increasing and nourishing the hair...." Indeed, it appears that the liquid extract of boiled dried Chinese anis is the only active ingredient, noting the fourth line of the abstract which states that the anis extract liquid is the active component. This does not suggest to the person of ordinary skill in the art that *lactobacillus* has any activity *per se* as a hair growth agent.

Applicant has discovered that not only is *lactobacillus* (and other lactic acid producing bacteria) effective in promoting hair growth, but that a particular portion of the bacteria, namely the cellular walls, contain more effective components capable of stimulating hair growth. Thus, the present invention utilizes the extract obtained from crushed cellular walls of the bacteria. In this regard, applicant's specification states as follows at the top of page 6:

In the present invention "filtrate of culture" means the liquid fraction of the lactic acid bacterial culture, obtained by crushing the bacterial cells present in the culture medium (bacterial suspension) to make them into a colloidal or dissolved form, and removing the cellular residue.

Also see page 9, lines 18-24, and page 11, lines 20-23.

Even in the unlikely event that the person of ordinary skill in the art, reading the Matsuoka abstract, would conclude that *lactobacillus per se* would stimulate hair growth, which applicant respectfully denies, this still would not reach the present invention because Matsuoka does not suggest using a culture filtrate of *lactobacillus*, especially a culture filtrate obtained from crushed cellular walls of the bacteria.

Chizik has not been cited to make up for the deficiencies of Matsuoka as discussed above, and indeed does not do so. Therefore, even if the proposed combination of Matsuoka and Chizik were obvious to the person of ordinary skill in the art at the time the present invention was made, such combination would not correspond to applicant's invention.

Withdrawal of the rejection is in order and is respectfully requested.

Applicant wishes to address one additional point mentioned in the second paragraph on page 3 of the Official Action, citing and relying on *In re Thrope*, 227 USPQ 964, 967 (Fed. Cir. 1985). This is significant with respect to applicant's new claims 7-10 which are in part product-by-process claims. *Thorpe* stands for the proposition that the

patentability of a product depends on the product and not on how it is made; with respect to product-by-process claims, the fact that the process *per se* may be patentable does not necessarily make the product patentable. The court stated in part as follows:

..., even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself [citations omitted]

The patentability of a product does not depend on its method of production. [citation omitted] If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the product was made by a different process. {citations omitted}

But the court did not say that all product-by-process claims are unpatentable. If it is clear from the record that the process produces a **product** which is different from the prior art product, then the product-by-process claim defines a novel product, i.e. the product may be properly characterized by its method of preparation, and will be patentable if novel and unobvious.

This was made clear in the case of *In re Luck et al*, 177 USPQ 523, 525 (CCPA 1973), wherein the Court stated:

As for the method of application, it is well established that product claims may include process steps to wholly or partially define the claimed product. {citation omitted} To the extent that these process limitations distinguish the **product** over the prior art,

they must be given the same consideration as  
traditional product characteristics.  
(emphasis in original)

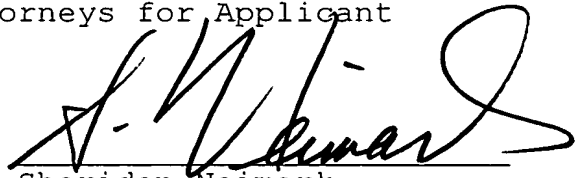
The process steps recited in applicant's product-by-process  
claims 7 and 8 clearly produce a different product from  
anything in the cited prior art. As indicated above, because  
more effective components necessary to hair growth are  
contained in the cellular walls of the bacteria, the crushing  
of the rigid cellular walls of the bacteria followed by  
extraction produces a hair growth tonic which is not only  
different but is also unexpectedly more effective.

Applicant respectfully requests favorable  
reconsideration and allowance.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant

By



Sheridan Neimark

Registration No. 20,520

SN:jaa  
Telephone No.: (202) 628-5197  
Facsimile No.: (202) 737-3528  
G:\BN\K\Kanf\HORIUCHI 4\PTO\amd se02.doc